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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,986	07/14/2003	David Boyd Melvin	MELV / 02CT	5972

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EXAMINER

CHATTOPADHYAY, URM

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/618,986

Applicant(s)

MELVIN, DAVID BOYD

Examiner

Urmi Chattopadhyay

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 13-20 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/20/03; 3/15/04; 9/7/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The first sentence of the specification regarding priority must be updated to include the most current status of each related application. Application 09/850,554 is now U.S. Patent No. 6,592,619, application 09/326,416 is now U.S. Patent No. 6,520,904, application 09/316,611 is now abandoned, application 09/165,887 is now U.S. Patent No. 6,221,103, and application 08/581,914 is now U.S. Patent No. 5,957,977. On page 2, line 1, "December 23, 1997" is inaccurate and must be changed to --January 2, 1997--.

2. The disclosure is objected to because of the following informalities:

- a) On page 3, line 16, "hart" must be changed to --heart--.
- b) On page 22, line 6, it appears that "block 106" should be changed to --block 106b--.
- c) On page 22, line 21, "Block 106b" must be changed to --block 106b--.
- d) On page 23, line 20, it appears that "Figure 8A" should be changed to --Figure 7A--.
- e) On page 25, line 11, "arrows 113" should be changed to --arrows 117-- according to Figure 8B.
- f) On page 28, line 3, "by" must be changed to --be--.
- g) On page 29, line 22, "apertures 113" should be changed to --apertures 121-- according to Figure 10C.
- h) On page 29, lines 22-23, "resilient member 115" should be changed to --resilient member 119-- according to Figure 10C.
- i) On page 31, line 9, it appears that "Figure 12B" should be changed to --Figure 11B--.

j) On page 36, line 5, "natur4al" must be changed to --natural--.

Appropriate correction is required.

Claim Objections

3. Claims 2, 3, 7, 8, 10 and 14 are objected to because of the following informalities:

a) Claim 2, line 1, "activation" must be changed to --actuation-- for consistent claim terminology.

b) Claim 3 is grammatically awkward; the examiner suggests rewording the claim to the following: "The actuation system of claim 1, wherein the actuator band is configured to extend along a portion of the left ventricle heart wall, and the band, in the actuated state, is configured to indent the wall and effect a reduction of the volume of the left ventricle.--

c) Claim 7, line 1, it appears that --one-- or --an-- should be inserted before "end".

d) Claims 7 and 8 seem to be claiming the same thing and are within the same scope.

e) Claim 10, line 2, "coupled" must be changed to --couple--.

f) Claim 14, line 2, a period is missing at the end of the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-11 and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 5 recites the limitation "the drive apparatus" in line 3. There is insufficient antecedent basis for this limitation in the claim.

6. Claims 7, 8 and 11 recite the limitation "the external framework element" in line 2 or 3. There is insufficient antecedent basis for this limitation in the claim. Claim 1, on which these claims depend, does not require the framework to be an external member.

7. Claim 17 is indefinite because on line 11, it is unclear how the paving element is "coupled between" the actuator band and the heart wall. Normally, an element is coupled "with" or "to" another element. According to the specification on page 27, lines 21-22, the paving membrane "might be utilized with the actuator band"; there is no support for the paving element being coupled to or with the actuator band. The examiner suggests amending the claim according to what is disclosed in the specification.

8. Claim 18 recites the limitation "the paving element" in line 1. There is insufficient antecedent basis for this limitation in the claim. It appears that the claim should be dependent on claim 17, rather than on claim 1 and will so be interpreted for examination purposes.

9. Claims 19 and 20 are indefinite because they fail to be dependent on a claim. It appears that they should be dependent on claim 17, and will so be interpreted for examination purposes.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-4, 7, 8 and 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Heilman et al. (USPN 5,383,840, as cited in applicant's IDS).

Heilman et al. discloses an actuation system (20) for assisting the operation of the natural heart (22) with all the elements of claims 1 and 17. See Figure 4A and column 4, lines 21-23 for a framework (138) interfacing with a natural heart (22). See Figure 5 and column 9, lines 55-60 for an actuator system (30) coupled to the framework (38) via sheath assembly (124) and configured to engage an exterior surface of the heart (22). See Figure 5, column 3, lines 4-22 and column 11, lines 49-61 for the actuator system (30) comprising an actuator band (38) extending along a portion of the heart wall exterior surface and selectively movable between an actuated state and a relaxed state and operable, when in the actuated state, to assume a predetermined shape and thereby indent a portion of the heart wall to effect a reduction in the volume of the heart (22). See column 6, lines 49-57 for a curvature limiting device (42) coupled to the actuator band (38) via rotatable support spool (36) and operable for limiting the curvature that the actuator band (38) imposes on the indented portion of the heart wall. See Figure 5, column 9, lines 33-43 and column 10, lines 3-15 for a paving element (130) between the actuator band (38) and the heart wall for providing a smooth functioning of the band with the heart wall.

Claim 2, see column 6, lines 40-57 for a drive apparatus (combination of 36 and 40) coupled to the actuator band (38) and operable for selectively moving the actuator band (38) between the relaxed and actuated states to achieve the desired assistance of the natural heart (22).

Claim 3, see Figure 5, column 7, lines 55-57 and column 3, lines 17-18 for the actuator band (38) being configured to extend along a portion of the left ventricle heart wall, and the band, in the actuated state, configured to indent the wall and effect a reduction of the volume of the ventricle.

Claim 4, see Figure 5 and column 8, lines 19-22 for the actuator band (38) including a plurality of juxtaposed elements (links), the elements configured to be drawn together in the actuated state and to cooperate with each other when drawn together to assume the predetermined shape (links of chain 138 are drawn together to form a shape with a smaller radius of curvature in the actuated state).

Claims 7 and 8, see Figure 5 and column 11, lines 22-24 for at least one end of the actuator band (38) being fixed to the framework (138) via housing (44) and sheath assembly (124) to which the framework (138) is attached (column 9, lines 55-59).

Claim 13, see column 6, lines 49-57 for the curvature limiting device (42) being operable for limiting the curvature of the actuator band (138) to a certain percentage of the natural curve of the portion of a heart wall exterior surface along which the actuator band (138) extends.

Claim 14, see column 3, lines 62-64 for a plurality of actuator bands (138) for indenting a portion of a heart wall.

Claim 15, see column 8, lines 21-22 for the actuator band (138) comprising a plurality of articulated elements (links), which move with respect to each other at joints.

Claim 16, see column 3, lines 19-22 and column 11, lines 60-61 for the actuator band (138), in the relaxed state, being operable to generally assume the natural curve of the heart wall surface along which the actuator band (138) extends.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilman et al. in view of Mortier et al. (USPN 6,260,552, as cited in applicant's IDS).

Heilman et al. discloses an actuation system (20) for assisting the operation of the natural heart (22) with all the elements of claim 17, but is silent to the paving element (130) being flexible, including a mesh, and including a fabric, as required by claims 18, 19 and 20, respectively. See column 10, lines 6-11 for the paving element being made from a material that is relatively porous in nature to enhance tissue ingrowth, such as polyurethane foam. Mortier et al. discloses a transventricular splint including tension members with anchor pads, wherein the anchor pads (612 or 340) are made from a Dacron fabric or are enclosed in an envelope (446) with the bottom layer (447) being made from mesh Dacron in order to promote tissue ingrowth from the heart wall surface. See Figures 53 and 78, column 21, lines 21-31 and column 26, lines 41-45. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the paving element be made from Dacron

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mesh or fabric, which are flexible by nature, as an alternative to polyurethane foam because applicant has not disclosed that the specified paving element material provides an advantage, is used for a particular purpose, or solves a stated problem over polyurethane foam. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the paving element being made from polyurethane foam, Dacron mesh or fabric or other porous materials because the ability for the material to enhance tissue ingrowth is not affected by using one of these materials over the other. Therefore, it would have been obvious to one of ordinary skill in the art to look to the teachings of Mortier et al. and an obvious matter of design choice to modify Heilman et al. to obtain the invention as specified in claims 18, 19 and 20.

Allowable Subject Matter

14. Claim 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

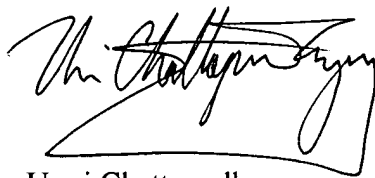
15. Claims 5, 6 and 9-11 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Urmi Chattopadhyay', enclosed within a rectangular box.

Urmi Chattopadhyay

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